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Registration Decision

RD2013-03

Pseudomonas fluorescens **strain CL145A**

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Registration Decision for *Pseudomonas fluorescens* strain CL145A

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Pseudomonas Fluorescens* Technical and Zequanox, containing the technical grade active ingredient *Pseudomonas fluorescens* strain CL145A, to control dreissenid mussels (Zebra and Quagga mussels) in industrial water structures.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2012-12, *Pseudomonas fluorescens strain CL145A*. This Registration Decision² describes this stage of the PMRA's regulatory process for *Pseudomonas fluorescens* strain CL145A and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2012-12. This decision is consistent with the proposed registration decision stated in PRD2012-12.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-12, *Pseudomonas fluorescens strain CL145A* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Zequanox?

Pseudomonas fluorescens strain CL145A is a bacterium used as a microbial pest control agent (MPCA) to control dreissenid mussels (zebra and quagga mussels) and their larvae in industrial water infrastructures.

The end-use product, Zequanox, is a commercial molluscicide that contains inactivated *Pseudomonas fluorescens* strain CL145A as the active ingredient. Zequanox is to be used in infrastructure water in hydroelectric dams for the control of quagga and zebra mussel fouling. Application is limited to once-through water cooling systems and fire sprinklers in hydro electric dams.

Health Considerations

Can Approved Uses of *P. fluorescens* strain CL145A Affect Human Health?

***Pseudomonas fluorescens* strain CL145A is unlikely to affect your health when Zequanox is used according to the label directions.**

People can be exposed to *P. fluorescens* strain CL145A when handling and applying Zequanox. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic byproducts); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies and the levels to which people may be exposed relative to exposures already encountered in nature to other strains of this microorganism. When *P. fluorescens* strain CL145A was tested on laboratory animals, a formulation very similar to the technical grade formulation was found to be not toxic to rats via the oral, pulmonary and dermal route, and is not expected to cause any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Strains of *P. fluorescens* are common in nature. As there are no direct applications to food, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals to *P. fluorescens* strain CL145A.

No risks are expected from exposure to *P. fluorescens* strain CL145A via drinking water because exposure will be negligible, with municipal treatment of drinking water likely removing any residues of the MPCA from the drinking water.

Occupational Risks From Handling Zequanox

Occupational risks are not of concern when Zequanox is used according to label directions, which include protective measures.

Workers using Zequanox can come into direct contact with *P. fluorescens* strain CL145A on the skin, in the eyes, or by inhalation. To minimize exposure, the label will specify that users exposed to Zequanox must wear eye protection, waterproof gloves, long-sleeved shirts, long pants, and shoes plus socks and a dust/mist filtering NIOSH approved respirator/mask (with any N-95, R-95, P-95 or HE filter).

For bystanders, exposure is expected to be much less than that of workers involved in mixing/loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Zequanox Is Introduced Into the Environment?

Environmental risks are not of concern.

Following application, the natural background levels of *Pseudomonas fluorescens* strain CL145A in the environment are unlikely to rise since the active ingredient contained in the end-use product, Zequanox, has been inactivated.

Studies were conducted to determine the effects of inactivated *P. fluorescens* strain CL145A on birds, fish and aquatic invertebrates. These studies showed that inactivated *P. fluorescens* strain CL145A was not toxic to birds, however, toxicity to fish and aquatic invertebrates was shown. Despite being toxic to aquatic organisms, no harm to aquatic organisms will occur from the use of Zequanox in hydroelectric dams since the expected environmental concentration (EEC) in aquatic ecosystems will not exceed 1 mg active ingredient (a.i.)/L (1 part per million [ppm]) which is below the concentration of inactivated *P. fluorescens* strain CL145A shown to be toxic to aquatic organisms.

Although terrestrial insect, earthworm, terrestrial and aquatic plant, and microorganism testing was not conducted, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected. Negligible exposure to inactivated *P. fluorescens* strain CL145A to terrestrial non-target organisms is expected and aquatic plants are not expected to be sensitive to the active ingredient at levels expected from the use of Zequanox in hydroelectric dams.

Value Considerations

What Is the Value of Zequanox?

Zequanox provides a biological alternative for the prevention of zebra and quagga mussel fouling in dams and power plants.

When applied at high cell densities ranging from 50–200 mg/L a.i., Zequanox is effective at reducing the degree of fouling from zebra and quagga mussels. It is particularly effective against larval mussels (i.e. pediveligers and juveniles) that have recently settled onto and attached to pipe surfaces. In the absence of control, the mussels settle in densely-packed colonies that impede the flow of water, reduce heat transfer and contribute to corrosion. The current treatment regime to control mussels in power plants and dams is typically the application of chlorine. While also effective, the chlorine treatment produces undesirable byproducts. Ontario Power Generation has in place a program to reduce their use of chlorine. Zequanox provides an effective treatment option without these byproducts.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Zequanox to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because of concerns with users developing allergic reactions through repeated high exposures to *P. fluorescens* strain CL145A, anyone handling, mixing/loading, or involved in clean-up/repair activities of Zequanox must wear eye protection, waterproof gloves, a long-sleeved shirt, long pants and a dust/mist filtering respirator/mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any N-95, R-95, P-95 or HE filter as a standard precaution.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-12, *Pseudomonas fluorescens strain CL145A*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.